generally disclosed as part of the published patent. A biosimilar manufacturer would have to have intimate knowledge of these proprietary processes in order to ''duplicate'' the biologic product, and even then it is extremely difficult—no two living cell lines are identical, so no two biologics manufacturing processes have identical starting materials or proceed in the same way.

It's also important to note that because biologics are produced with cells from living organisms, many of them can cause an immune reaction which is normally benign and does not affect safety. However, some of these reactions can negate the effectiveness of the biologic or even cause side effects that are more dangerous. Most of these reactions can only be observed through clinical trials with real patients.

Any expedited regulatory pathway for biosimilars must account for all these factors and I'm proud to join with the Ranking Member of the Energy and Commerce Committee, Rep. JOE BARTON, to introduce the Pathway for Biologics Act. Our bill builds on the significant progress the Senate, led by Senators KENNEDY and ENZI, has already made, as well as the significant level of consensus we have heard on our Committee about this issue. The Pathway for Biologics Act will establish a new statutory pathway for biosimilars guided by three principles:

1. Legislation to facilitate the development of biosimilars should promote competition and lower prices, but patient safety, efficacy and sound science must be paramount.

2. We must preserve incentives for innovation and ensure that patients will continue to benefit from the groundbreaking treatments biotechnology alone can bring.

3. We must strive to protect the rights of all parties and resolve disputes over patents in a timely and efficient manner that does not delay market entry and provides certainty to all parties.

The regulatory pathway set forth in the Pathway for Biologics Act embodies each of these principles and sets forth a sensible, scientifically sound process for approval of biosimilars. The legislation allows for input from all interested parties and provides FDA appropriate flexibility to protect patient health by requesting analytical, animal and clinical studies to demonstrate the safety, purity and potency of a biosimilar. The FDA will be empowered to require the tests and data it deems necessary, but the results of clinical testing for immunogenicity will always be required as part of this data unless the FDA has published final guidance documents advising that such a determination is feasible in the current state of science absent clinical data and explaining the data that will be required to support such a determination. Since biologics are derived from human and animal products, immune reactions are a major concern for any new biologic product and are now impossible to detect without actual human testing.

Our legislation also addresses the important issue of interchangeability of biosimilars for the reference product. Some legislative proposals would allow the FDA to permit pharmacists and insurers to substitute a biosimilar for a physician's prescription for an innovator biologic product even when they cannot be demonstrated to be identical in their composition or effectiveness. Interchangeability of generic pharmaceuticals for brand name drugs is entirely appropriate since traditional generic drugs are chemically identical to the reference product. However, if the state of science is such that a complex molecule cannot be fully characterized and a precursor biologic cannot be adequately compared to a proposed biosimilar, then the biosimilar should not be fully substitutable for the precursor product without a physician's direction. The Pathway for Biologics Act makes it clear that the FDA cannot make a determination that a biosimilar is interchangeable with a reference product until it has published final guidance documents advising that it is feasible in the current state of scientific knowledge to make such determinations with respect to the relevant product class and explaining the data that will be required to support such a determination. This requirement is consistent with the recommendations of the Secretary of Health and Human Services.

An essential element of any new regulatory scheme for the biotech industry is a careful balancing of incentives for innovation and opportunities for new entry by competitors. To preserve incentives for innovation, the Pathway for Biologics Act provides 12 years of data exclusivity for new biologic products, which ensures that biosimilar applications that rely on the safety and efficacy record of existing biologic products will not be permitted to enter the market for 12 years following the approval of the innovator product. The 12-year exclusivity period is meant to preserve existing protections biotech companies receive from patents. The Congressional Budget Office has found that the effective patent life for pharmaceuticals is about 11.5 years, so a data exclusivity period of 12 years is consistent with that finding. Data exclusivity is necessary to provide additional protections and incentives for biologics because biosimilars—unlike generic drugs—will not be chemically identical to the reference product and will be less likely to infringe the patents of the innovator.

The legislation also includes incentives for additional indications and pediatric testing. New indications are critical for biologics and are often more significant than the indications for which approval was granted. Incentives for continued testing on new indications must be included to promote access to new treatments and cures, and this bill provides an additional 2 years exclusivity for new indications. I also believe it's important to provide incentives similar to those given traditional pharmaceuticals under the Best Pharmaceuticals for Children Act to biologics, so the legislation provides an additional 6 months of data exclusivity for testing for use in pediatric groups.

In order to protect the rights of all parties and ensure that all patent disputes involving a biosimilar are resolved before the expiration of the data exclusivity period, the Pathway for Biosimilars Act establishes a simple, streamlined patent resolution process. This process would take place within a short window of time—roughly 6–8 months after the biosimilar application has been filed with the FDA. It will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large. The legislation also preserves the ability of third-party patent holders such as universities and medical centers to defend their patents.

Once a biosimilar application is accepted by the FDA, the agency will publish a notice identifying the reference product and a designated agent for the biosimilar applicant. After an exchange of information to identify the relevant patents at issue, the applicant can decide to challenge any patent's validity or applicability. All information exchanged as part of this procedure must be maintained in strict confidence and used solely for the purpose of identifying patents relevant to the biosimilar product. The patent owner will then have two months to decide whether to enforce the patent. If the patent owner's case is successful in court, the final approval of the application will be deferred until the patent expires.

Madam Speaker. I believe the Pathway for Biosimilars Act sets forth a straightforward, scientifically based process for expedited approval of new biologics based on innovative products already on the market. This new biosimilars approval pathway will promote competition and lower prices, but also ensure that patients are given safe and effective treatments that have been subjected to thorough scrutiny and testing by the FDA. The Pathways for Biosimilars Act will also protect the rights of patent holders and preserve incentives for innovation in the biotechnology sector to develop the next generation of life-saving, life-changing therapies.

I strongly urge my colleagues to support the Pathway for Biosimilars Act.

RECOGNIZING MARCELLA POTTHOFF OF INDIANOLA, IOWA, AS THE GOOD SAMARITAN SOCIETY'S 2007 VOLUNTEER OF THE YEAR

HON. TOM LATHAM

OF IOWA

IN THE HOUSE OF REPRESENTATIVES

Thursday, March 13, 2008

Mr. LATHAM. Madam Speaker, I rise today to recognize and congratulate Marcella Potthoff of Indianola, Iowa, as the Good Samaritan Society's 2007 Volunteer of the Year.

Marcella volunteers three days every week at the Indianola Good Samaritan Center. She performs a variety of tasks for residents, which includes making food, pushing wheelchairs and playing games. She especially enjoys bingo. According to Trudie Wood, the activity director and volunteer coordinator at the Good Samaritan Center, Marcella's eagerness to serve, and her patience and availability at short notice is what makes Marcella deserving of this award.

Marcella has dedicated her life to improving her community. Her past volunteer work includes teaching Sunday school, hosting a Bible study, helping with youth activities, leading a Girl Scout troop, and being an active member in a quilt club and a singles club. She is a great example for her community, and I commend her on her enduring commitment.

I consider it an honor to represent Marcella Potthoff in Congress. I commend Marcella's willingness to volunteer and I wish her all the best in her future endeavors.